Translation

PATENT COOPERATION TRE



PCT 10/53245

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference					
3104WO0P	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)				
International application No. PCT/JP2003/013528	International filing date (day/month/year) Priority date (day/month/year) 23 October 2003 (23.10.2003) 25 October 2002 (25.10.2002)				
International Patent Classification (IPC) or na	23 October 2003 (23.10.2003) 25 October 2002 (25.10.2002)				
C07K 16/18, C12N 15/09, 5/10, 0 25/16, 25/18, 25/20, 25/22, 25/24	112P 21/08 A 61K 20/205 A 61P 0/00 0/00 0/00				
Applicant					
TAK	EDA CHEMICAL INDUSTRIES, LTD.				
This international preliminary examinand is transmitted to the applicant acc	ation report has been prepared by this International Preliminary Examining Authority ording to Article 36.				
2. This REPORT consists of a total of	sheets, including this cover sheet.				
This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).					
These annexes consist of a total					
3. This report contains indications relating	to the following items:				
I Basis of the report					
II Priority					
III Non-establishment of o	pinion with regard to novelty, inventive step and industrial applicability				
IV Lack of unity of invent					
V Reasoned statement un citations and explanation	er Article 35(2) with regard to novelty, inventive step or industrial applicability;				
VI Certain documents cited					
VII Certain defects in the in	ernational application				
VIII Certain observations on the international application					
Date of submission of the demand	Date of completion of this report				
25 November 2003 (25.11.2					
Name and mailing address of the IPEA/JP	Authorized officer				
Facsimile No.	Telephone No.				
orm PCT/IPS A /400 (cover short) (T. L. 1000)					

Form PC1/1P2A/409 (cover sheet) (July 1998)

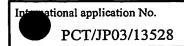
INTERNATIONAL PRIMINARY EXAMINATION REPORT

- 1	
	ational application No.
	PCT/IP2003/013529

I. Basis of the	report
	to the elements of the international application:*
the in	ternational application as originally filed
	escription:
pages pages	as originally filed
pages	filed with the demand
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pages	filed with the demand
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	, filed with the letter of, filed with the demand, the language, all the elements marked above were available or furnished to this Authority in the language in which
the lang or 55.3) With regard of preliminary examples of the state of	guage of a translation furnished for the purposes of international search (under Rule 23.1(b)). guage of publication of the international application (under Rule 48.3(b)). guage of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/ to any nucleotide and/or amino acid sequence disclosed in the international application, the international amination was carried out on the basis of the sequence listing: ed in the international application in written form. gether with the international application in computer readable form. d subsequently to this Authority in written form. d subsequently to this Authority in computer readable form. tement that the subsequently furnished written sequence listing does not go beyond the disclosure in the onal application as filed has been furnished. ement that the information recorded in computer readable form is identical to the written sequence listing has nished.
the the the the	e description, pagese e claims, Nose drawings, sheets/fig thas been established as if (some of) the amendments had not been made, since they have been considered to go e disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**
placement she this report as d 70.17).	sets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to s "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16
y i epiacement	sheet containing such amendments must be referred to under item 1 and annexed to this report.
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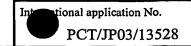
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III. Non-e	III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability						
1. The quindustr	1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:						
	the entire international application.						
\boxtimes	claims Nos						
becaus							
\boxtimes	the said international application, or the said claims Nos. 22, 23 relate to the following subject matter which does not require an international preliminary examination (specify):						
diagnost	The subject matters of claims 22 and 23 relate to a method for treatment of the human body or a diagnostic method, which does not require an international preliminary examination by the International Preliminary Examining Authority in accordance with PCT Article 34 (4)(a)(i) and Rule 67.1(iv).						
	the description, claims or drawings (Indicate particular elements below) or said claims Nos are so unclear that no meaningful opinion could be formed (specify):						
	the claims, or said claims Nos are so inadequately supported by the description that no meaningful opinion could be formed.						
\boxtimes	no international search report has been established for said claims Nos						
2. A mea sequer	uningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid nee listing to comply with the standard provided for in Annex C of the Administrative Instructions: the written form has not been furnished or does not comply with the standard. the computer readable form has not been furnished or does not comply with the standard.						

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NO

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement 1. Statement					
	Claims	1-6, 18-21	NO		
Inventive step (IS)	Claims		YES		
	Claims	1-21, 24	МО		
Industrial applicability (IA)	Claims	1-21, 24	YES		

2. Citations and explanations

Document 1: EP, 1241479, A2 (ABC Armbruster Biochemicals), 18 September, 2002 (18.09.02), full text Document 2: EP, 1136503, A1 (Takeda Chemical Industries, Ltd.), 26 September 2001, (26.09.01), full text Document 3: WO, 01-04298, A1 (Takeda Chemical Industries, Ltd.), 18 January, 2001 (18.01.01), full text Document 4: WO, 01-37780, A2 (Smithkline Beecham Corp.), 31 May, 2001 (31.05.01), full text

Claims

The subject matters of claims 1-6 and 18-21 do not appear to be novel or to involve an inventive step in view of documents 1-3 cited in the ISR.

Document 1 describes a monoclonal antibody and a polyclonal antibody against urotensin II having an amino acid sequence corresponding to the SEQ ID NOS: 1 and 9 of the present application, and also describes that the antibodies are used for detecting urotensin II. (Especially, see SEQ ID NOS: 2 and 1.)

Document 2 describes a monoclonal antibody and a polyclonal antibody against the peptide having an amino acid sequence corresponding to the SEQ ID NOS: 1-4 and 6 of the present application, and also describes that (1) the antibodies are used for detecting and determining the said polypeptide, and (2) the antibodies are also used as diagnostic agents for the diseases to which the said polypeptide relates. (Especially, see SEQ ID NOS: 22, 7, 8, 21 and 39, pages 55-63, the claims.)

Document 3 describes a monoclonal antibody and a polyclonal antibody against the peptide having an amino acid sequence corresponding to the SEQ ID NOS: 5 and 8 of the present application, and also describes that (1) the antibodies are used for detecting and determining the said polypeptide, and (2) the antibodies are also used as diagnostic agents for the diseases to which the said polypeptide relates. (Especially, see SEQ ID NOS: 5 and 27, pages 46-53 and the claims).

The subject matters of claims 1-21 and 24 do not appear to involve an inventive step in view of documents 1-4 cited in the ISR.

Document 4 describes the polypeptide having an amino acid sequence corresponding to the SEQ ID NO: 7 of the present application as human urotensin II analogue. (Especially, see SEQ ID NO: 11.)

Documents 1-4 belong to the same technical field in view of urotensin II and its method of usage. So, a person skilled in the art could have easily conceived of (1) obtaining an antibody against the peptide in the invention described in document 4 based on the inventions described in documents 1-3 and (2) using the antibody for detecting antigens and diagnosing the diseases to which urotensin II analogue relates.

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Sur	ple	men	tal	Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: V.2

Furthermore, it is also publicly known due to documents 1-4 that urotensin II relates to various diseases. So, a person skilled in the art could have easily (1) obtained a specific antibody capable of neutralizing the function of urotensin II for the purpose of preventing and curing the diseases to which urotensin relates, based on the inventions described in documents 1-4, and (2) used the obtained antibody as a preventive/remedy for the diseases to which urotensin II relates.